REMARKS

This Response and Petition for an Extension of Time are submitted in response to the Office Action mailed on March 25, 2005 having a shortened statutory response period that ended on June 25, 2005. This Response is timely filed within one month of the shortened statutory response period, namely July 25, 2005. The Commissioner is hereby authorized to charge any additional fees to Deposit Account number 02-1818.

Claims 76-78, 80-94 and new claims 105-108 are pending in this application.

Claims 76-78, 80-87, 90, and 91 were rejected under 35 U.S.C. § 103(a) for allegedly being obvious over U.S. Patent No. 6,800,245 to Erbe et al. (*Erbe*) in view of U.S. Patent No. 5,620,425 to Hefferman et al. (*Heffernan*) and U.S. Patent No. 3,780,308 to Nablo (*Nablo*). Claims 88-89 were rejected under 35 U.S.C. § 103(a) for allegedly being obvious over *Erbe*, in view of *Heffernan*, *Nablo*, and in further view of U.S. Patent No. 6,164,044 to Porfano et al. (*Porfano*). Claims 92-94 were rejected under 35 U.S.C. § 103(a) for allegedly being obvious over *Erbe* in view of *Heffernan* and *Nablo* and in further view of U.S. Patent No. 5,207,983 to Liebert et al. (*Liebert*). Applicants respectfully disagree with and traverse these alleged rejections as no combination of *Erbe*, *Heffernan*, *Nablo*, *Porfano*, and *Liebert* teaches or suggests the subject matter recited in the present claims.

Erbe, Heffernan, Nablo, Porfano, and *Liebert*, either alone or in combination, fail to teach or suggest a production method for sterilizing and filling syringes that includes transferring sterilized syringe bodies into an isolator class 100 sterile environment while maintaining the sterility of the syringe bodies as recited in the present claims. *Erbe* discloses a method for preparing a kit that includes filling paste into cartridges in a sterile environment. The cartridges may be sterilized prior to the filling process. *Erbe*, col. 11 lines 40-63, col. 12 lines 19-27. *Erbe*, however, has no disclosure whatsoever regarding the transfer of the cartridges into the sterile environment, let alone maintaining the syringe bodies in a sterile condition during transfer into the sterile environment. As *Erbe* is wholly silent regarding the transfer of the cartridges into the sterile environment, *Erbe* does not teach or suggest maintaining sterilized syringe bodies in a sterile condition during transfer into a sterile environment as recited in the present claims.

Neither *Heffernan* nor *Nablo* teaches or suggests a syringe filling method that includes transferring sterilized syringe bodies into an isolator class 100 sterile environment while maintaining the sterility of the syringe bodies as recited in the present claims. *Heffernan* has no

disclosure that sterilized syringe bodies are transferred into a sterile environment from a sterilizing location. Indeed, *Heffernan* suggests the contrary as the entire *Heffernan* production process (*i.e.*, from syringe body molding to the sealing of filled syringes) takes place in a single clean room. *Heffernan*, col. 1 line 65 through col. 2 line 2, col. 5 line 50 through col. 7 line 14. As 1) *Heffernan* has no disclosure regarding the transfer of sterilized syringe bodies into a sterile environment, and 2) *Heffernan's* syringe bodies are molded, filled and sealed in a single clean room, *Heffernan* suggests that sterile syringe bodies are not transferred into a sterile environment, contrary to the subject matter recited in the present claims.

Similarly, *Nablo* fails to teach or suggest maintaining the sterility of sterilized syringe bodies while transferring the syringe bodies into a sterile environment as recited in the claims. *Nablo* discloses a method for surface sterilizing packaging material with electron beam radiation. *Nablo*, col. 1 lines 3-8. The emission of electron beam radiation creates a sterile environment or zone within the *Nablo* process system. *Nablo*, col. 5 lines 58-68, FIGS. 4, 5a, 5b, 5c (*see* reference numeral 4). *Nablo*, however, has no disclosure or suggestion that the packaging material entering the sterile environment is sterile.

Porfano and *Liebert* fail to remedy the deficiencies of *Erbe*, *Heffernan*, and *Nablo*. *Porfano* teaches away from the recited method for filling syringes as *Porfano* discloses a method for producing a prefilled syringe that includes transferring molded syringe barrels to a sterile environment without any sterilization. *Porfano*, col. 10 lines 43-62. *Liebert* lacks any disclosure remotely related to 1) sterilization by electron beam radiation and 2) transfer of sterile syringe bodies into a sterile environment. Thus, no combination of *Erbe*, *Heffernan*, *Nablo*, *Porfano*, and *Liebert* teaches or suggests the subject matter recited in the present claims.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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